Informed Consent Statement

Journal: World Journal of Hepatology

Manuscript NO: 36557

Title: Impact of Sustained Virologic Response on Chronic Kidney Disease Progression in Hepatitis C

Column: Retrospective Study

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This study was approved by the VA Institutional Review Board and the Research and Development Committee at VA Greater Los Angeles Health System (VAGLAHS) – IRB Number 2016-100938. Due to the retrospective nature of this study, an exempt for informed consent was approved by the VA institutional review board. See attached IRB statement.

Elizabeth Aby

Department of Veterans Affairs

Memorandum

Date: February 21, 2017

From: Chair, Institutional Review Board-Bc

Subj: PCC 2016-100938, *Identification and Characterization of Risk Factors for the Development of Non-alcoholic Fatty Liver Disease (NAFLD) Phenotypes Utilizing Administrative Databases*

To: Joseph R. Pisegna, MD (151)

1. This application has been approved by the Chair or by a designated reviewer through expedited review as outlined in VHA Handbook 1200.05 dated November 14, 2014, which is in keeping with 38 CFR 16.110 and 21 CFR 56.110 because the research procedures as described meet criteria in accordance with 45 CFR 46.110(f) Category 5, research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). **This approval will expire February 20, 2018.**

2. Further, review of the application indicates that the activities in this project (or the remaining activities in this project): 1) present no more than minimal risk to human subjects (i.e. the magnitude of harm or discomfort anticipated are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological tests); 2) Identification of the subjects and/or their responses would NOT reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal; and 3) the research is not classified. This information has been forwarded to the ACOS for notification of approval.

3. **Additional determinations made by the IRB:**

   a. *A modification must be submitted to the IRB for analysis of archival tissue specimen for approval prior to implementation.*

   b. The Chair or designee found it acceptable for the study to collect social security numbers from the Coporate Data Warehouse for the purposes of this study.

   c. The Chair or designee has determined that the PI has justified the granting of a waiver of consent for the entire study in accordance with 45 CFR 46.116d which requires that 1) the research involve no more than minimal risk to the subjects; 2) the waiver or alteration will not adversely affect the rights and welfare of the subjects; 3) the research could not practicably be carried out without the waiver or alteration; and 4) it is not anticipated that there will be a need to provide subjects pertinent information at the completion of the study.

   d. The Chair or designee has determined that a waiver of HIPAA authorization for the entire study under 45 CFR 164.512 (i) (2) (ii) was appropriate in that the use or disclosure of the